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Using structured data entry systems in the electronic medical record to collect clinical data for quality and research: Can we efficiently serve multiple needs for complex patients?

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Abstract

Purpose: The era of the electronic health record (ERH) generates the ability to systematically collect and record innumerable data for complex procedures such as videourodynamic studies (VUDS). We developed a Structured Data Entry System (SDES) that would serve as a way to better standardize VUDS for both quality improvement and research capabilities.

Methods: A working group convened to design a SDES form for VUDS in a flow sheet format in our hospital's EHR, allowing for easy integration of the information into the clinical encounter note and for a weekly export of data to clinicians in spreadsheet form.

Results: Analysis of weekly VUDS data revealed that entries were missing in 3% of cells in all SDES forms completed. The availability of the data in an Excel spreadsheet allows for easy manipulation, calculation of clinical variables, and streamlined analysis in figures or graphs to identify patients at the highest risk.

Conclusion: Designing and implementing a SDES based on a flowsheet that can allow data to seamlessly be placed in the clinical record and to be integrated into a searchable database for quality improvement and research purposes, allows one to harness the true potential of the EHR.

Keywords

electronic medical records; standardized data entry system; urodynamics; pediatric urology; health information technology

Introduction

Certain studies are difficult to interpret in the aggregate due to the huge amount of information that they contain; a videourodynamic study (VUDS) is an example of such a

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challenge. This becomes even more challenging if the formal interpretation of the tracing is left until after the urodynamics session is completed. As shown in several studies, and in an interactive presentation by Dr. Stacy Tanaka at the 2017 Spina Bifida Association meeting, the interpretation of the cystometrogram after the fact only increases the chances for greater inter-observer variability and possible intra-observer variability as well(1). In addition, after one has performed hundreds of studies, how can one begin to categorize the subsets of patients without looking at each record? In this era of the electronic health record (EHR), we can do better in terms of identifying these subsets, but only if we can commit to standardizing the test conditions and the means of recording the data which ideally would be done during the actual encounter.

EHR platforms allow use of structured data entry systems (SDES) which allow data entry based on predefined categories and conditions. While SDES can be employed to generate patient history or physical examination findings, they can also be used in the development of specific flow sheets tailored to a certain disease process or procedure. SDES allow for uniformity and standardization of data entry and collection which in turn allows for easier reporting of that data and use in templated notes for the EHR(2).

Developing and utilizing a SDES is critical for both optimizing delivery of top-quality patient care and collecting data for research endeavors. A properly designed SDES can decrease research costs, increase patient-oriented research, and facilitate medical advancements without compromising privacy, the completeness, or accuracy of the EHR (3). Murray and Berberian have proposed four steps to creating a usable SDES: 1) Institute a clinical advisory committee to develop and maintain standards for clinical protocols for clinical information within EHR, 2) Identify the “deal breakers” for structured data entry, especially in regards to physician resistance, 3) Identify the workflows to facilitate data entry capture, and 4) Identify the technology platforms necessary for seamless integration, often with the help of information technology or services departments(4).

With these steps in mind and with the understanding that medical record keeping must be focused around the patient at the time of the encounter, and cannot be purely focused on the research questions, we set out with the goal of building a SDES that we could populate in real time during the videouroydnamic encounter that would do the following:

1. Calculate expected bladder capacity and the volumes representing 25,50, and 75% of the expected bladder capacity based on our entry of the patient’s weight in Kg which we would enter at the start of the visit
2. Transform the data we enter into a progress note to fulfill our duty to document the encounter for legal and billing purposes
3. Result in a searchable data base that could be sent to us weekly by Information Services (IS).

Our goal was to develop a SDES capable of serving a patient care function by allowing for a better standardization of the study, a safety function by allowing periodic assessment of the most hostile bladders, as well as a research function.

Materials and Methods

A working group of three pediatric urologists and two nurses who specialize in the caring for the child with spina bifida were convened to ask what data should be recorded and a trial was undertaken for 3 months using a simple template modification in EPIC (Epic Systems Corp., Madison, Wisconsin), the EHR employed at our institution, to see how this would impact on work flow during the VUDS encounter. Important parameters and data for entry were discussed among the group and included if consensus reached by majority of the group. During the 3 month trial period, as studies were being performed additional parameters deemed important for inclusion were discussed with the group and added to the form if consensus reached. Once this was done, hospital informatics joined us to help design a template SDES form in a flow sheet format with drop down menus for descriptive variables (Figure 1). This allowed for calculations of expected bladder capacity as well as the volumes at 25,50, and 75% of estimated bladder capacity based on weight (Estimated bladder capacity [in cc] = patient weight in Kg × 7). In addition, the flow sheet will automatically tally the voided (or leaked) volume (if any) as well as the residual urine determined by aspiration at the end of the study. This total volume is then subtracted from the infused volume to arrive at the volume of urine produced during the actual study. This value can be substantial depending upon the degree of diuresis a patient may be experiencing either as a result of a post obstructive diuresis effect or because of the variabilities in the state of hydration.

All studies were conducted by the attending physician and data was entered in real time as each check point was reached during the urodynamic study. Images captured during the study are stored in the GE fluoroscopic system and then transmitted to the department of radiology for final interpretation and storage. The flow sheet is then transferred into a prepopulated area of a clinic progress note upon completion of the VUDS study (Figure 2). The progress note also contains areas for the physical examination as well as free texting to describe the indications for the study and the current medical and social issues as well as the final impression and plan. As a result of how the data is stored within the flow sheets, information systems can send us a weekly summary of all the VUDS we have completed in a CSV delimited format for easy use in programs such as Excel (© & (P) 1998–2007 Microsoft Corporation, Redmond, Washington) (Figure 3). This data can also be entered into REDCap (Research Electronic Data Capture) which then allows for sharing across multi-institutional trials. REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. In addition, there is no information loss as the actual urodynamic tracing with associated images is also scanned into EPIC in a PDF file for permanent storage and it can be retrieved for further analysis as needed.

Data was analyzed using Stata 14.2 (StataCorp, College Station, Texas) and continuous variables were analyzed using the Wilcoxon rank-sum test and dichotomous variables using Pearson’s chi-squared test. Significance was set at $p<0.05$.

Results

Over the past 18 months we completed a total of 316 urodynamic studies for patients with spina bifida. All studies were completed using SDES form and information was inputted into the form in real-time during the urodynamic study by the pediatric urology attending. At the end of each week, the data from each VUDS was delivered via email to one attending who compiled the data into one complete database. Overall, analysis of the columns of data revealed that entries were missing in 3% of cells. *This data accrual rate was achieved by physician data entry alone*; no research assistant has monitored the weekly data feed to go back and fill in any missing values. We have encouraged physicians to leave cells empty if they could not be populated with certainty.

To demonstrate the ease at which the entered SDES data can be used for potential research purposes, we performed several simple analyzes of the complied database of all 316 urodynamic studies in consecutive SB patients. Of these patients, 74 had undergone a prenatal and 242 had undergone a postnatal closure. A table was then generated to compare percentage of expected bladder capacity reached at end of study, presence of vesicoureteral reflux and presence of detrusor overactivity during the study between the SB patients who underwent prenatal vs. postnatal closure (**Table 1)**. Bladder capacity attained for the two groups and the presence of vesicoureteral reflux did not differ between the prenatal and postnatal closure cohorts (Table 1). Statistical analysis can then easily be performed on this collected data as shown in Table 1.

In addition to providing VUDS data in an easily sortable and analyzable fashion, the SDES complied information allows for quick assessment of the reliability and precision of the data as well as inter-observer agreement. For instance, any parameter or data in the SDES form can be pulled such as bladder neck status on fluoroscopic images or bladder pressure at 50% expected bladder capacity and a second physician can review the original VUDS study to determine inter-observer agreement. This allows the SDES form and data to be used in quality control or improvement projects.

As with any SDES form and implementation there are potential limitations. First, at our institution the attending pediatric urologist is present for all urodynamic studies and inputs all data into the SDES in real time during the study. This policy may not be the same at other institutions and the robustness and reliability of data entry by other health care providers was not tested in our study.

Discussion

While adoption of EHR systems was already spreading by the late 2000s, the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009 as part of the American Recovery and Reinvestment Act accelerated that growth by offering incentives as well as penalties for failure to convert to an EHR by 2015(5). In fact, by 2014 97% of all hospitals and 75% of all physicians nationwide were using certified EHR technology(6). As a consequence of this widespread adoption of EHR, the amount of electronically stored patient data available for quality improvement, research, and outcomes

analysis has also increased dramatically. Unfortunately, many EHR systems were initially designed with billing and reimbursement purposes in mind and thus adaption of these systems for clinical assessment and improvement has not always been smooth. Additionally, physician attitudes towards EHR, and the use of structured data entry systems (SDES) within the EHR, will vary across specialties and age groups and may further be a barrier to successful implementation in clinical practice and research(3).

Given the complexity of and important clinical information acquired from urodynamic studies (UDS), it is a model procedure for implementation of a SDES. VUDS and UDS without fluoroscopy are important tools in the pediatric urologist skillset to objectively evaluate the lower urinary tract function in children. While there is no consensus on indications for UDS, these studies are often employed in various clinical scenarios and are helpful in both non-neurogenic and neurogenic bladder dysfunction(7, 8). Retrieval of data from these, and other, complex studies can be accomplished if the study is standardized via an easy to use and accurate SDES and if the data is stored in the EHR in a flowsheet template that can be retrieved on a regular basis. This allows for the analysis of complex subsets of patients on an ongoing basis.

Recently, the International Children's Continence Society (ICCS) published a guideline for the standardization of the measurement, quality control, and documentation of UDS in children(9). With these recommendations and those of the International Continence Society (ICS)'s "Good Urodynamic Practices" in mind, we created a SDES in the form of a flow sheet to be filled out during the UDS in real-time. The design of this SDES flow sheet followed the four principles outlined by Murray and Berberian and which are described above(4). The important data points for collection and clinical protocol for UDS were defined by the spina bifida working group at our institution, a multidisciplinary group of physicians and nurses. Barriers to implementation including physician resistance were minimized by creating an easy to use flow sheet that can be filled out during the study so that no additional time is added to the patient encounter. The entire department (both physicians and non-physician providers involved in UDS) was taught the proper workflows to obtain and capture the data for the SDES during the urodynamic study. Lastly, with collaboration from the information services department the ability to integrate the SDES into the encounter/procedure note in the EHR was established as well as the automated system for collecting and disseminating the weekly reports via email.

In this study we have shown that a structured data entry system in real time for a complex diagnostic test like VUDS can yield high quality data with minimal disruption of patient care. The total time it took to analyze the datasets for this report was under 2 hours which is very efficient when one compares this to what it might have taken if we were to have to open up each individual study and abstract the data one cystometrogram at a time. As an example analysis, we compiled specific parameters and characteristics of interest between spina bifida patients who had undergone postnatal versus prenatal closures. While statistical analyzes of this data are shown in table 1, this was done as a proof of concept and not to draw conclusions about differences between the SB populations.

Analyze of the weekly compiled datasets showed that approximately 3% of all cells have missing values, but often this is because there is no appropriate entry for the value. In some instances, the failure to enter data was an oversight at the time of the urodynamic study and review of the missing cells on a weekly basis allows for these data points to be filled in accurately in the chart. Ideally, a research assistant could curate the data set on a weekly basis. If an assistant were to review the 6–8 studies per week that are done in the division, the accuracy of the data set would only get better, and this could be accomplished with a short time commitment making this an efficient investment of research funds. It is also critical to remember that all tracings and recordings from the VUDS system are stored separately and available for review, so there is no chance for information loss.

We have learned some lessons along the way that we would share with other groups seeking to enter such data. First and foremost is the need for all the providers involved in these studies to discuss what information they are committed to banking away. In retrospect we probably put away more information than we could handle with entries for shunt status, infections, bowel management history, and orthopedic status. Some patient data and characteristics such as age at the time of the study should be easy to autopopulate directly from the EHR. One important note is that we did not build in a hard stop that would prevent an EPIC encounter for being closed if the urodynamics flowsheet was not filled out. The reason for this is that we did not want to create an incentive for rapidly filling in cells just to get an encounter closed to keep up with the workflow. It is better to leave a cell empty, and then have the data added later by the weekly review of the data by a research assistant than to quickly put in data that is not accurate.

The essence of any successful SDES lies in its ability to standardize or make data collection uniform across patients through an easy reporting system while allowing for improved decision support, real-time quality assessment, and opportunities for patient-oriented clinical research(2, 11). Ideally, a well-designed SDES should facilitate quality improvement whether in a hospital setting or a clinical practice. Batalden and Davidoff define the goals of “quality improvement” as making changes that lead to “better patient outcomes (health), better system performance (care), and better professional development (learning)”(12). The ease of both collecting and reviewing UDS data in our SDES flow sheet, makes it the perfect model for implementing quality improvement projects via the “plan-do-study-act” (PDSA) approach(13). From a quality improvement standpoint, our UDS SDES can allow for the identification of the patients at highest risk of renal damage. Furthermore, this systematic approach to data collection also allows us to bank urine samples from well characterized phenotypes in a search for biomarkers that would be predictive of a progressive loss of compliance. Future projects in a PDSA approach can focus on any of the numerous questions still surrounding pediatric UDS such as can we identify risk factors at time of study for post-UDS urinary tract infections or can we identify predictors of which children with neurogenic bladder will require management/treatment change based on UDS results.

Conclusion

The era of the EHR brings with it the ability to systematically collect and record innumerable amounts of data especially for complex procedures such as VUDS. Designing

and implementing a structured data entry system based on a flow sheet that can both allow the data to seamlessly be placed in the electronic medical note and be integrated into a searchable database for quality improvement and research purposes, allows one to harness the true potential of the EHR. Minimization of physician resistance by creating a data entry system that is easy to use without increasing time burden will ensure compliance and use of the SDES.

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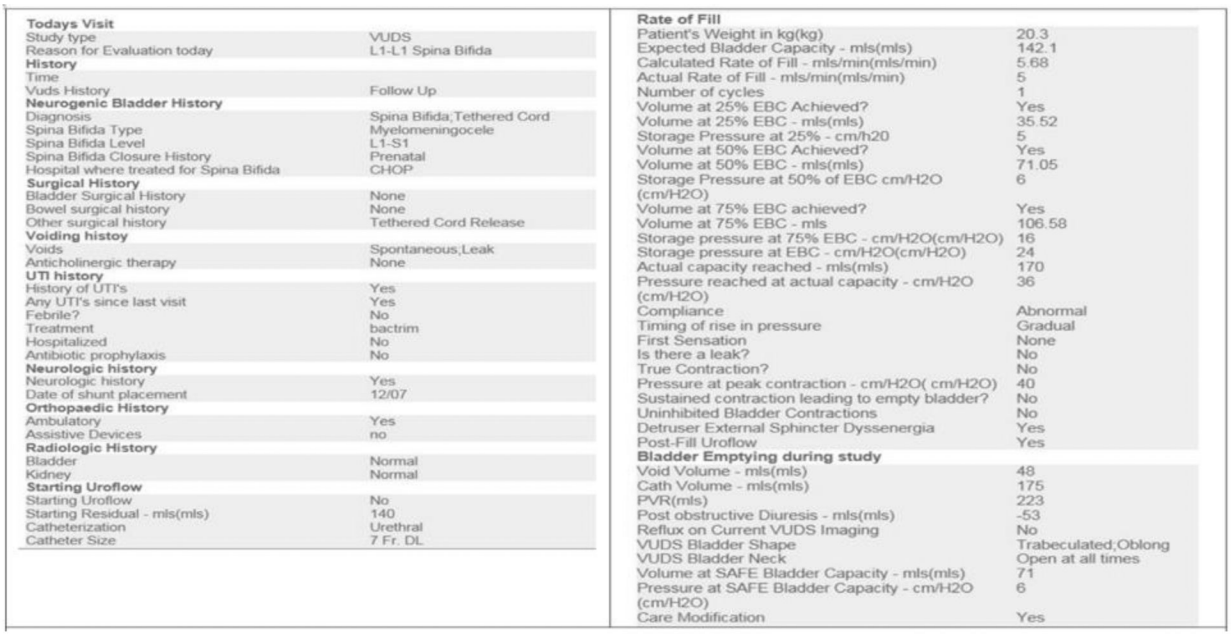
Figure 1.

An example of the structured data entry system, an easy to use flow sheet that can be opened up in the patients EHR and allows for prompted entry of data in real-time during the UDS or VUDS. Note that by including body weight, the flow sheet will automatically compute the EBC as well as the volumes at 25,50 and 75% of the expected capacity.



Todays Visit	
Study type	VUDS
Reason for Evaluation today	L1-L1 Spina Bifida
History	
Time	
Vuds History	Follow Up
Neurogenic Bladder History	
Diagnosis	Spina Bifida;Tethered Cord
Spina Bifida Type	Myelomeningocele
Spina Bifida Level	L1-S1
Spina Bifida Closure History	Prenatal
Hospital where treated for Spina Bifida	CHOP
Surgical History	
Bladder Surgical History	None
Bowel surgical history	None
Other surgical history	Tethered Cord Release
Voiding histoy	
Voids	Spontaneous;Leak
Anticholinergic therapy	None
UTI history	
History of UTI's	Yes
Any UTI's since last visit	Yes
Febrile?	No
Treatment	bactrim
Hospitalized	No
Antibiotic prophylaxis	No
Neurologic history	
Neurologic history	Yes
Date of shunt placement	12/07
Orthopaedic History	
Ambulatory	Yes
Assistive Devices	no
Radiologic History	
Bladder	Normal
Kidney	Normal
Starting Uroflow	
Starting Uroflow	No
Starting Residual - mls(mls)	140
Catheterization	Urethral
Catheter Size	7 Fr. DL

Rate of Fill	
Patient's Weight in kg(kg)	20.3
Expected Bladder Capacity - mls(mls)	142.1
Calculated Rate of Fill - mls/min(mls/min)	5.68
Actual Rate of Fill - mls/min(mls/min)	5
Number of cycles	1
Volume at 25% EBC Achieved?	Yes
Volume at 25% EBC - mls(mls)	35.52
Storage Pressure at 25% - cm/h20	5
Volume at 50% EBC Achieved?	Yes
Volume at 50% EBC - mls(mls)	71.05
Storage Pressure at 50% of EBC cm/H2O (cm/H2O)	6
Volume at 75% EBC achieved?	Yes
Volume at 75% EBC - mls	106.58
Storage pressure at 75% EBC - cm/H2O(cm/H2O)	16
Storage pressure at EBC - cm/H2O(cm/H2O)	24
Actual capacity reached - mls(mls)	170
Pressure reached at actual capacity - cm/H2O (cm/H2O)	36
Compliance	Abnormal
Timing of rise in pressure	Gradual
First Sensation	None
Is there a leak?	No
True Contraction?	No
Pressure at peak contraction - cm/H2O(cm/H2O)	40
Sustained contraction leading to empty bladder?	No
Uninhibited Bladder Contractions	No
Detruser External Sphincter Dyssenergia	Yes
Post-Fill Uroflow	Yes
Bladder Emptying during study	
Void Volume - mls(mls)	48
Cath Volume - mls(mls)	175
PVR(mls)	223
Post obstructive Diuresis - mls(mls)	-53
Reflux on Current VUDS Imaging	No
VUDS Bladder Shape	Trabeculated;Oblong
VUDS Bladder Neck	Open at all times
Volume at SAFE Bladder Capacity - mls(mls)	71
Pressure at SAFE Bladder Capacity - cm/H2O (cm/H2O)	6
Care Modification	Yes

Figure 2.

After completion of the study and the SDES, the information recorded is instantly populated in the EHR note for that visit with the click of a button. This documentation fulfills the legal and insurance claims needs. A personalized narrative and plan are added in the same note.

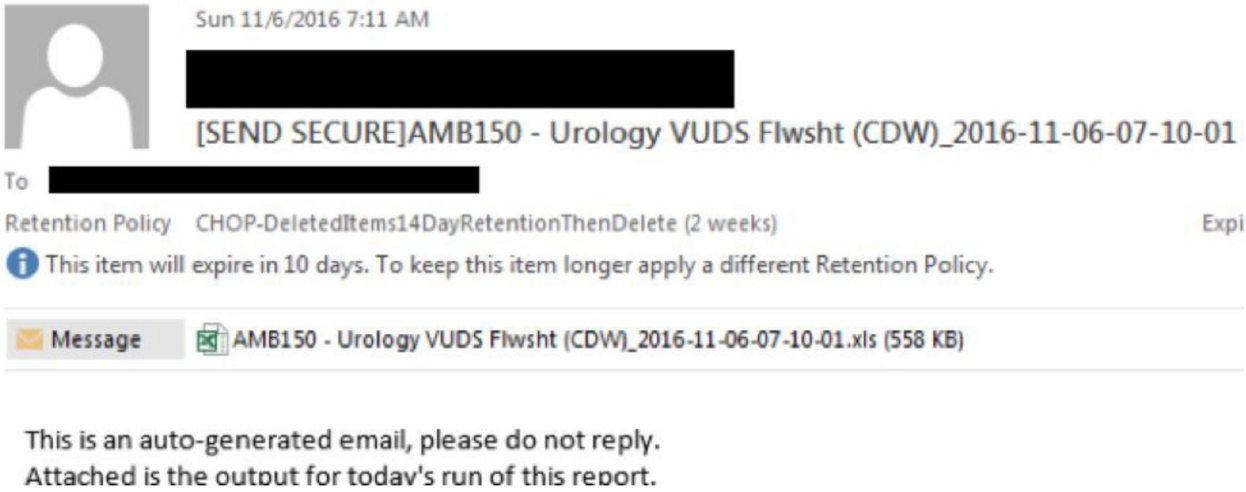


Figure 3.

The data from the SDES flow sheets are accrued into an excel spread sheet that is automatically emailed to pediatric urology team weekly.

Table 1.

Videourodynamic study findings in patients based on timing of surgical closure.

	Postnatal Closure N = 242	**Prenatal Closure N = 74**	**P value**
% of EBC achieved (median, [IQR])	0.98 [0.66 – 1.05]	0.98 [0.63 – 1.13]	NS
Reflux	18.3%	11.5%	0.15
Overactive Bladder	57.1%	73.9%	0.008

IQR = interquartile range